

MAR 22 2002

K020580

BIOMET
CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Phone: (574) 267-6639

Proprietary Name: X-Series Bi-Metric® Hip Femoral Components

Common Name: Hip replacement prosthesis

Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, porous coated uncemented (888.3558)

Legally Marketed Device to which Substantial Equivalence is Claimed: Bi-Metric® Hip Femoral Component (K921224)

Device Description: The X-Series Bi-Metric® femoral components are identical to the predicate Bi-Metric® femoral components in overall geometry. Both device series are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-620. The stem diameters and lengths are identical. An oblong insertion hole replaces the predicate round insertion hole in order to provide the surgeon with more control during insertion.

For the new lateralized style, the difference in the two series lies in the horizontal offsets and neck angle. The offset is increased and therefore the distance from the center of the modular head to the center of the stem is also increased. The taper trunion or post is angled at 130° on the modified device whereas the post of the predicate device is at 135°.

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P.O. Box 587
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56 E. Bell Drive
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219.267.6639

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219.267.8137

E-MAIL
biomet@biomet.com

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Intended Use: Non-cemented use for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

Summary of Technologies: The technological characteristics (materials, design, sizing and indications) of the X-Series Bi-Metric femoral components are similar to or identical to the predicate device.

Non-Clinical Testing: Mechanical testing was conducted to insure the design changes would not effect the safety of the device.

Clinical Testing: None provided



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K020580

Trade/Device Name: X-Series Bi-Metric® Hip Femoral Components

Regulation Number: 21 CFR §888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH

Dated: February 20, 2002

Received: February 21, 2002

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

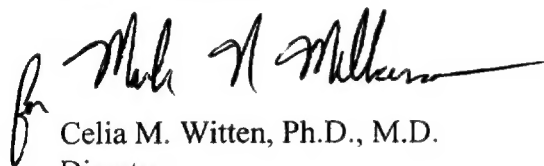
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Patricia Sandborn Beres

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized initial "C" and a long horizontal flourish extending to the right.

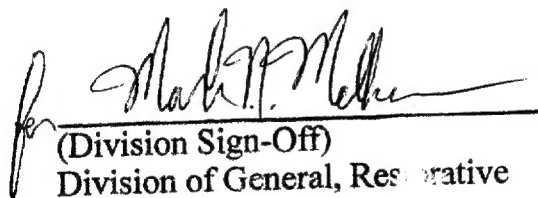
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K020580

Device Name: X-Series Bi-Metric Femoral Components

Indications For Use:

Non-cemented use for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020580

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

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